

Russell Davis (SBN 177959)
PACIFIC JUSTICE INSTITUTE
29 Lakewood Ave.
San Francisco, CA 94127
Tel. (415) 310-6575
rdavis@pji.org

Kevin T. Snider (SBN 170988)
PACIFIC JUSTICE INSTITUTE
P.O. Box 276600
Sacramento, CA 95827
Tel. (916) 857-6900
Fax (916) 857-6902
ksnider@pji.org

Attorneys for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

SHANNON HARTMAN, KATIE LIGHTFOOT,
MD,

Plaintiffs,

v.

SANTA CLARA COUNTY; PAUL E. LORENZ,
Executive Director of Santa Clara Valley Medical
Center, in his official capacity only; DR. DAVID
JACOBSON, Director of Medicine Residency at
Santa Clara Valley Medical Center, in his official
capacity only; JEFFREY V. SMITH, County
Executive for Santa Clara County, in his official
capacity only; DOES 1-100,

Defendants.

) Case No.: 4:22-cv-01587-JSW

)

) **DECLARATION OF RUSSELL DAVIS**
) **IN SUPPORT OF PLAINTIFFS'**
) **MOTION FOR PRELIMINARY**
) **INJUNCTION**

)

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) Date: July 8, 2022
) Time: 9:00 AM
) Courtroom: 5

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DECLARATION OF RUSSELL DAVIS

Russell Davis declares:

1. I am the attorney of record in the above matter. I have personal knowledge of the facts in this matter, and if called to testify about them, I would and could do so competently.

2. Attached as Exhibit 1 herein is a true and correct copy of a *New England Journal of Medicine* article on the resurgence of SARS-COV-2 infection in Highly Vaccinated Health System Workforce. The article underscores the importance of masking and testing.

3. Attached as Exhibit 2 herein is a true and correct copy of a CDC bulletin re: breakthrough infections among vaccinated residents that had traveled to a large public event. The bulletin suggests that universal masking in indoor public settings should be an expanded prevention strategy.

4. Attached as Exhibit 3 herein is a true and correct copy of an ABC News analysis regarding COVID-19 deaths among vaccinated persons.

5. Attached as Exhibit 4 herein is a true and correct copy of the California Department of Public Health directive of January 8, 2022.

6. Attached as Exhibit 5 herein a true and correct copy of a CDC publication regarding breakthrough cases of COVID-19 in vaccinated persons.

7. Attached as Exhibit 6 herein is a true and correct copy of a *Lancet* article regarding the transmission of COVID-19 among fully vaccinated individuals.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 23rd day of May 2022 in San Francisco, California.

/s/ Russell Davis

Russell Davis, Esq.
PACIFIC JUSTICE INSTITUTE

Attorney for Plaintiffs

EXHIBIT 1



Editor's Note: This letter was published on September 1, 2021, at NEJM.org.

CORRESPONDENCE

Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce

September 30, 2021

N Engl J Med 2021; 385:1330-1332

DOI: 10.1056/NEJMc2112981

Metrics

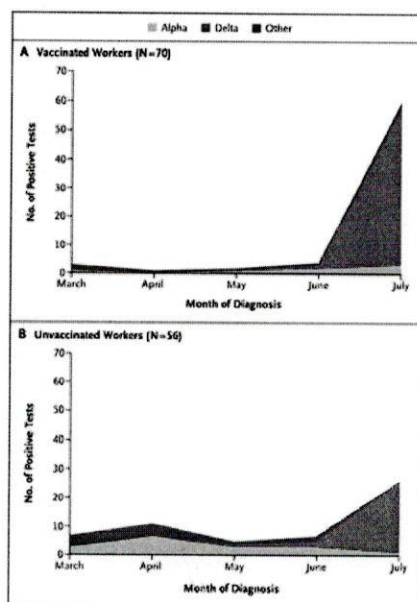
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TO THE EDITOR:

Figure 1.



SARS-CoV-2 Variants among Symptomatic Health Workers.

In December 2020, the University of California San Diego Health (UCSDH) workforce experienced a dramatic increase in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. Vaccination with mRNA vaccines began in mid-December 2020; by March, 76% of the workforce had been fully vaccinated, and by July, the percentage had risen to 87%. Infections had decreased dramatically by early February 2021.¹ Between March and June, fewer than 30 health care workers tested positive each month. However, coincident with the end of California's mask mandate on June 15 and the rapid dominance of the B.1.617.2 (delta) variant that first emerged in mid-April and accounted for over 95% of UCSDH isolates by the end of July (Figure 1), infections increased rapidly, including cases among fully vaccinated persons. Institutional review board approval was obtained for use of administrative data on vaccinations and case-investigation data to examine mRNA SARS CoV-2 vaccine effectiveness.

UCSDH has a low threshold for SARS-CoV-2 testing, which is triggered by the presence of at least one symptom during daily screening or by an identified exposure, regardless of vaccination status. From March 1 to July 31, 2021, a total of 227 UCSDH health care workers tested positive for SARS-CoV-2 by reverse-transcriptase–quantitative polymerase-chain-reaction (RT-qPCR) assay of nasal swabs; 130 of the 227 workers (57.3%) were fully vaccinated. Symptoms were present in 109 of the 130 fully vaccinated workers (83.8%) and in 80 of the 90 unvaccinated workers (88.9%). (The remaining 7 workers were only partially vaccinated.) No deaths were reported in either group; one unvaccinated person was hospitalized for SARS-CoV-2–related symptoms.

Table 1.

	March	April	May	June	July
UCSDH workforce—no. of persons	18,394	18,592	18,080	18,085	18,024
Vaccination status—no. of persons					
Fully vaccinated	14,470	15,512	14,127	16,426	16,460
mRNA (2/3) (n=10,404)	5,568	7,065	7,160	7,401	7,404
Non-mRNA (2/3) (n=4,000)	1,902	8,447	6,967	9,025	9,056
Unvaccinated	3,924	3,080	3,953	1,659	1,564
Percentage of workers fully vaccinated	78.5	81.1	80.9	90.9	90.7
Symptomatic Covid-19					
Fully vaccinated workers	9	6	9	5	9
Unvaccinated workers	11	17	30	10	12
Percentage of cases w/ fully vaccinated workers	21.4	26.0	23.1	33.3	43.2
Attack rate per 1000 (95% CI)					
Fully vaccinated workers	0.21 (0.07–0.47)	0.26 (0.09–0.60)	0.19 (0.11–0.43)	0.30 (0.01–0.55)	0.7 (0.4–0.9)
Unvaccinated workers	0.4 (0.1–0.6)	0.6 (0.4–0.9)	0.9 (0.6–1.2)	0.6 (0.4–0.7)	1.6 (1.1–2.1)
Vaccine effectiveness—% (95% CI)	66.7 (50.3–81.9)	66.7 (51.7–80.1)	66.7 (51.7–80.1)	66.7 (51.7–80.1)	66.7 (51.7–80.1)

^a UCSDH denotes University of California San Diego Health.
^b Data are the total number of workers who had received two doses of an mRNA vaccine as of the last day of the month.

Symptomatic SARS-CoV-2 Infection and mRNA Vaccine Effectiveness among UCSDH Health Workers, March through July 2021.

Vaccine effectiveness was calculated for each month from March through July; the case definition was a positive PCR test and one or more symptoms among persons with no previous Covid-19 infection (see the **Supplementary Appendix**). Vaccine effectiveness exceeded 90% from March through June but fell to 65.5% (95% confidence interval [CI], 48.9 to 76.9) in July (Table 1). July case rates were analyzed according to the month in which workers with Covid-19 completed the vaccination series; in workers completing vaccination in January or February, the attack rate was 6.7 per 1000 persons (95% CI, 5.9 to 7.8), whereas the attack rate was 3.7 per 1000 persons (95% CI, 2.5 to 5.7) among those who completed vaccination during the period from March through May. Among unvaccinated persons, the July attack rate was 16.4 per 1000 persons (95% CI, 11.8 to 22.9).

The SARS CoV-2 mRNA vaccines, BNT162b2 (Pfizer–BioNTech) and mRNA-1273 (Moderna), have previously shown efficacy rates of 95% and 94.1%,² respectively, in their initial clinical trials, and for the BNT162b2 vaccine, sustained, albeit slightly decreased effectiveness (84%) 4 months after the second dose.³ In England, where an extended dosing interval of up to 12 weeks was used, Lopez Bernal et al. reported a preserved vaccine effectiveness of 88% against symptomatic disease associated with the delta variant.⁴ As observed by others in populations that received mRNA vaccines according to standard Emergency Use Authorization intervals,⁵ our data suggest that vaccine effectiveness against any symptomatic disease is considerably lower against the delta variant and may wane over time since vaccination.

The dramatic change in vaccine effectiveness from June to July is likely to be due to both the emergence of the delta variant and waning immunity over time, compounded by the end of masking requirements in California and the resulting greater risk of exposure in the community. Our findings underline the importance of rapidly reinstating nonpharmaceutical interventions, such as indoor masking and intensive testing strategies, in addition to continued efforts to increase vaccinations, as strategies to prevent avoidable illness and deaths and to avoid mass disruptions to society during the spread of this formidable variant. Furthermore, if our findings on waning immunity are verified in other settings, booster doses may be indicated.

Jocelyn Keehner, M.D.

Lucy E. Horton, M.D., M.P.H.

UC San Diego Health, San Diego, CA

Nancy J. Binkin, M.D., M.P.H.

UC San Diego, La Jolla, CA

Louise C. Laurent, M.D., Ph.D.

UC San Diego Health, San Diego, CA

for the SEARCH Alliance

David Pride, M.D., Ph.D.

Christopher A. Longhurst, M.D.

Shira R. Abeles, M.D.

Francesca J. Torriani, M.D.

UC San Diego Health, San Diego, CA

ftorriani@health.ucsd.edu

Disclosure forms provided by the authors are available with the full text of this letter at NEJM.org.

This letter was published on September 1, 2021, and updated on September 3, 2021, at NEJM.org.

EXHIBIT 2

Weekly / August 6, 2021 / 70(31);1059-1062

On July 30, 2021, this report was posted online as an MMWR Early Release.

Catherine M. Brown, DVM¹; Johanna Vostok, MPH¹; Hillary Johnson, MHS¹; Meagan Burns, MPH¹; Radhika Gharpure, DVM²; Samira Sami, DrPH²; Rebecca T. Sabo, MPH²; Noemi Hall, PhD²; Anne Foreman, PhD²; Petra L. Schubert, MPH¹; Glen R. Gallagher, PhD¹; Timelia Fink¹; Lawrence C. Madoff, MD¹; Stacey B. Gabriel, PhD³; Bronwyn MacInnis, PhD³; Daniel J. Park, PhD³; Katherine J. Siddle, PhD³; Vaira Harik, MS⁴; Deirdre Arvidson, MSN⁴; Taylor Brock-Fisher, MSc⁵; Molly Dunn, DVM⁵; Amanda Kearns⁵; A. Scott Laney, PhD² (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Variants of SARS-CoV-2 continue to emerge. The B.1.617.2 (Delta) variant is highly transmissible.

What is added by this report?

In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not.

What are the implications for public health practice?

Jurisdictions might consider expanded prevention strategies, including universal masking in indoor public settings, particularly for large public gatherings that include travelers from many areas with differing levels of SARS-CoV-2 transmission.

During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine ≥ 14 days before exposure). Genomic sequencing of specimens from 133 patients identified the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, in 119 (89%) and the Delta AY.3 sublineage in one (1%). Overall, 274 (79%) vaccinated patients with breakthrough infection were symptomatic. Among five COVID-19 patients who were hospitalized, four were fully vaccinated; no deaths were reported. Real-time reverse transcription-polymerase chain reaction (RT-PCR) cycle threshold (Ct) values in specimens from 127 vaccinated persons with breakthrough cases were similar to those from 84 persons who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 22.77 and 21.54, respectively). The Delta variant of SARS-CoV-2 is highly transmissible (1); vaccination is the most important strategy to prevent severe illness and death. On July 27, CDC recommended that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial.* Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding

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Figures

Figure 1

Figure 2

References

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prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

During July 3–17, 2021, multiple summer events and large public gatherings were held in a town in Barnstable County, Massachusetts, that attracted thousands of tourists from across the United States. Beginning July 10, the Massachusetts Department of Public Health (MA DPH) received reports of an increase in COVID-19 cases among persons who reside in or recently visited Barnstable County, including in fully vaccinated persons. Persons with COVID-19 reported attending densely packed indoor and outdoor events at venues that included bars, restaurants, guest houses, and rental homes. On July 3, MA DPH had reported a 14-day average COVID-19 incidence of zero cases per 100,000 persons per day in residents of the town in Barnstable County; by July 17, the 14-day average incidence increased to 177 cases per 100,000 persons per day in residents of the town (2).

During July 10–26, using travel history data from the state COVID-19 surveillance system, MA DPH identified a cluster of cases among Massachusetts residents. Additional cases were identified by local health jurisdictions through case investigation. COVID-19 cases were matched with the state immunization registry. A cluster-associated case was defined as receipt of a positive SARS-CoV-2 test (nucleic acid amplification or antigen) result ≤ 14 days after travel to or residence in the town in Barnstable County since July 3. COVID-19 vaccine breakthrough cases were those in fully vaccinated Massachusetts residents (those with documentation from the state immunization registry of completion of COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices,[†] ≥ 14 days before exposure). Specimens were submitted for whole genome sequencing[§] to either the Massachusetts State Public Health Laboratory or the Broad Institute of the Massachusetts Institute of Technology and Harvard University. Ct values were obtained for 211 specimens tested using a noncommercial real-time RT-PCR panel for SARS-CoV-2 performed under Emergency Use Authorization at the Broad Institute Clinical Research Sequencing Platform. On July 15, MA DPH issued the first of two Epidemic Information Exchange notifications to identify additional cases among residents of U.S. jurisdictions outside Massachusetts associated with recent travel to the town in Barnstable County during July 2021. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

By July 26, a total of 469 COVID-19 cases were identified among Massachusetts residents; dates of positive specimen collection ranged from July 6 through July 25 (Figure 1). Most cases occurred in males (85%); median age was 40 years (range = <1–76 years). Nearly one half (199; 42%) reported residence in the town in Barnstable County. Overall, 346 (74%) persons with COVID-19 reported symptoms consistent with COVID-19.^{**} Five were hospitalized; as of July 27, no deaths were reported. One hospitalized patient (age range = 50–59 years) was not vaccinated and had multiple underlying medical conditions.^{††} Four additional, fully vaccinated patients^{§§} aged 20–70 years were also hospitalized, two of whom had underlying medical conditions. Initial genomic sequencing of specimens from 133 patients identified the Delta variant in 119 (89%) cases and the Delta AY.3 sublineage in one (1%) case; genomic sequencing was not successful for 13 (10%) specimens.

Among the 469 cases in Massachusetts residents, 346 (74%) occurred in persons who were fully vaccinated; of these, 301 (87%) were male, with a median age of 42 years. Vaccine products received by persons experiencing breakthrough infections were Pfizer-BioNTech (159; 46%), Moderna (131; 38%), and Janssen (56; 16%); among fully vaccinated persons in the Massachusetts general population, 56% had received Pfizer-BioNTech, 38% had received Moderna, and 7% had received Janssen vaccine products. Among persons with breakthrough infection, 274 (79%) reported signs or symptoms, with the most common being cough, headache, sore throat, myalgia, and fever. Among fully vaccinated symptomatic persons, the median interval from completion of ≥ 14 days after the final vaccine dose to symptom onset was 86 days (range = 6–178 days). Among persons with breakthrough infection, four (1.2%) were hospitalized, and no deaths were reported. Real-time RT-PCR Ct values in specimens from 127 fully vaccinated patients (median = 22.77) were similar to those among 84 patients who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 21.54) (Figure 2).

Transmission mitigation measures included broadening testing recommendations for persons with travel or close contact with a cluster-associated case, irrespective of vaccination status; local recommendations for mask use in indoor settings, irrespective of vaccination status; deployment of state-funded mobile testing and vaccination units in the town in Barnstable County; and informational outreach to visitors and residents. In this tourism-focused community, the Community Tracing Collaborative^{¶¶} conducted outreach to hospitality workers, an international workforce requiring messaging in multiple languages.

The call from MA DPH for cases resulted in additional reports of cases among residents of 22 other states who had traveled to the town in Barnstable County during July 3–17, as well as reports of secondary transmission; further analyses are ongoing. As of July 3, estimated COVID-19 vaccination coverage among the eligible population in Massachusetts was 69% (3). Further

investigations and characterization of breakthrough infections and vaccine effectiveness among this highly vaccinated population are ongoing.

Top

Discussion

The SARS-CoV-2 Delta variant is highly transmissible (1), and understanding determinants of transmission, including human behavior and vaccine effectiveness, is critical to developing prevention strategies. Multipronged prevention strategies are needed to reduce COVID-19–related morbidity and mortality (4).

The findings in this report are subject to at least four limitations. First, data from this report are insufficient to draw conclusions about the effectiveness of COVID-19 vaccines against SARS-CoV-2, including the Delta variant, during this outbreak. As population-level vaccination coverage increases, vaccinated persons are likely to represent a larger proportion of COVID-19 cases. Second, asymptomatic breakthrough infections might be underrepresented because of detection bias. Third, demographics of cases likely reflect those of attendees at the public gatherings, as events were marketed to adult male participants; further study is underway to identify other population characteristics among cases, such as additional demographic characteristics and underlying health conditions including immunocompromising conditions.*** MA DPH, CDC, and affected jurisdictions are collaborating in this response; MA DPH is conducting additional case investigations, obtaining samples for genomic sequencing, and linking case information with laboratory data and vaccination history. Finally, Ct values obtained with SARS-CoV-2 qualitative RT-PCR diagnostic tests might provide a crude correlation to the amount of virus present in a sample and can also be affected by factors other than viral load.*** Although the assay used in this investigation was not validated to provide quantitative results, there was no significant difference between the Ct values of samples collected from breakthrough cases and the other cases. This might mean that the viral load of vaccinated and unvaccinated persons infected with SARS-CoV-2 is also similar. However, microbiological studies are required to confirm these findings.

Event organizers and local health jurisdictions should continually assess the need for additional measures, including limiting capacity at gatherings or event postponement, based on current rates of COVID-19 transmission, population vaccination coverage, and other factors.⁵⁵⁵ On July 27, CDC released recommendations that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial. Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

Top

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Top

Corresponding author: Catherine Brown, catherine.brown@mass.gov.

Top

¹Massachusetts Department of Public Health; ²CDC COVID-19 Response Team; ³Broad Institute, Cambridge, Massachusetts; ⁴Barnstable County Department of Health and the Environment, Massachusetts; ⁵Community Tracing Collaborative, Commonwealth of Massachusetts.

Top

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Stacey B. Gabriel reports receiving grants from CDC. Bronwyn MacInnis, Katherine Siddle, and Daniel Park report receiving grants from CDC and the National Institutes of Health. Taylor Brock-Fisher reports receiving a grant from the Community Tracing Collaborative. No other potential conflicts of interest were disclosed.

Top

* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

EXHIBIT 3

WND

ABC News analysis: COVID deaths rising among vaccinated

Wall Street Journal also reports increase in highly-vaccinated regions



By Art Moore

Published May 11, 2022 at 8:10pm



Hospital Corpsman 2nd Class Dillon Leggett, left, administers the COVID-19 vaccine to Intelligence Specialist 2nd Class Tairis Jacofernandez aboard the USS Hershel 'Woody' Williams in Rijeka, Croatia, March 30, 2021. (U.S. Navy photo by Mass Communication Specialist 2nd Class Eric Coffey)

An analysis by ABC News of federal data found that a growing proportion of COVID-19 deaths are occurring among the vaccinated.

Meanwhile, the Wall Street Journal reported that areas of the country with the highest vaccination rates, such as Northern New England states, "are coping with elevated cases and hospitalizations as the latest highly contagious iterations of the virus circulate."

ABC News assured its audience that "experts said the increase in breakthrough deaths is expected with more Americans reaching full vaccination status."

Case 4:22-cv-01587-JSW Document 19-2 Filed 05/23/22 Page 13 of 29
ABC News contributor, Dr. John D. Hensley, the medical director of Boston Children's Hospital, said the data "should not be interpreted as vaccines not working."

"In fact, these real-world analyses continue to reaffirm the incredible protection these vaccines afford especially when up to date with boosters," he said.

However, many of the most highly vaccinated nations, such as New Zealand and Israel, have seen a surge in cases amid the wave of omicron variants.

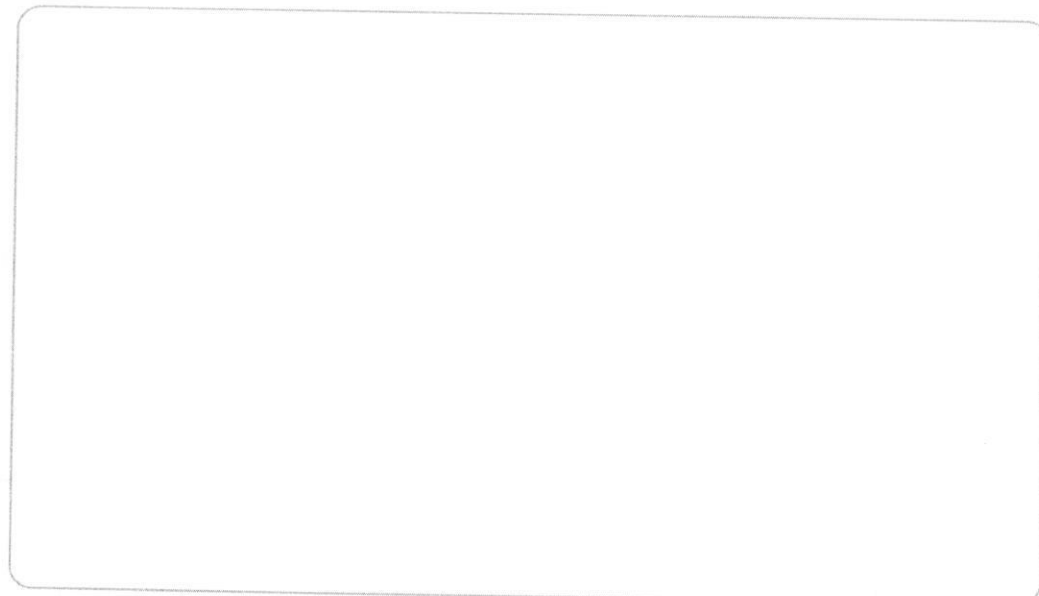
Portugal, which last year "had virtually no one left to vaccinate," the New York Times reported, currently has one of the highest COVID-19 case rates in the world.

Ian Miller
@ianmSC



7.5 months ago, the New York Times reported that Portugal had "virtually no one left to vaccinate." A few weeks later, Politico said "vaccination is the main determinant of whether a country can keep cases down"

Portugal currently has one of the highest case rates in the world



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See the latest COVID-19 information on Twitter

Are COVID booster shots merely intended to harm people?

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The ABC story cited Biden's top medical adviser, Dr. Anthony Fauci telling Boston Public Radio on Monday, "Given the fact that immunity is waning, we've got to get people boosted."

However, last month a top FDA official said a fourth COVID booster shot should be seen as a "stop gap" measure, concluding "we simply can't be boosting people as frequently as we are."

Meanwhile, CDC and U.K. government data have indicated that the COVID-19 vaccines not only are ineffective in preventing cases and transmission, they rapidly lose protection against severe illness or death while posing risks.

A newly published long-term study by the prestigious British journal The Lancet that followed up on participants in the Moderna and Pfizer trials found the vaccines had no effect on overall mortality.

An analysis of CDC data by Dr. Meryl Nass found vaccinated Californians and New Yorkers were three times more likely to develop COVID than those who had prior immunity and were unvaccinated.

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Further, vaccinated Californians had a higher rate of hospitalizations than those who were unvaccinated but had prior immunity. New York did not provide hospitalization data.

Case 4:22-cv-01587-JSW Document 19-2 Filed 05/23/22 Page 15 of 29
that says the composition of the current COVID-19 vaccines might need to be changed to ensure high levels of protection.

President Biden and CDC Director Rochelle Walensky assured Americans when the vaccines were rolled out that if you get vaccinated – for a disease that the CDC says has a survival rate of nearly 100% for people without chronic comorbidities – you won't get infected and you won't transmit the virus.

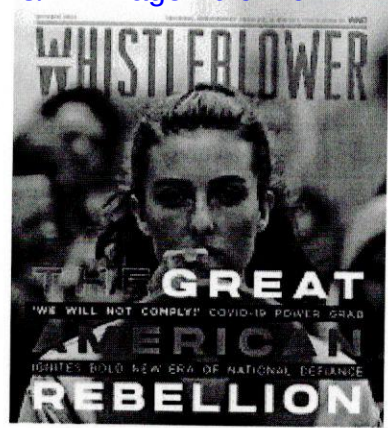
That clearly hasn't turned out to be true, confirming the censored warnings of scientists such as Dr. Robert Malone and Dr. Peter McCullough, who in January observed the "crumbling" establishment narrative that included "false statements regarding asymptomatic spread, reliance on lockdown and masks – which obviously didn't work – the suppression of early treatment, the mass promotion of vaccines that failed."

And Walensky had to admit at a recent forum that the CDC exercised "too little caution and too much optimism" about the effectiveness of the vaccines in preventing infection, transmission and deaths. And she acknowledged science isn't "black and white," it's "gray," and "sometimes it takes months and years to actually find out the answer."

In March, a former adviser to the FDA commissioner who continues to serve in an oversight role said the agency is ignoring its requirement to disclose clear safety and efficacy problems with the COVID-19 vaccines. Also in March, an Army flight surgeon testified in federal court that she was ordered by high-level command not to discuss the controversy over Department of Defense data indicating a massive spike in serious injuries and illnesses among military personnel when the vaccines were rolled out in 2021. And, mounting reports of serious injury and death on the CDC's vaccine-injury website, an analysis of CDC data by a former Wall Street executive and an insurance industry expert shows an alarming rise in excess deaths among Millennials over the past year coinciding the COVID vaccine rollout.

EDITOR'S NOTE: Last year, America's doctors, nurses and paramedics were celebrated as frontline heroes battling a fearsome new pandemic. Today, under Joe Biden, tens of thousands of these same heroes are

denounced as rebels, conspiracy theorists, extremists and potential terrorists. Along with massive numbers of police, firemen, Border Patrol agents, Navy SEALs, pilots, air-traffic controllers, and countless other truly essential Americans, they're all considered so dangerous as to merit termination, their professional and personal lives turned upside down due to their decision not to be injected with the experimental COVID vaccines. Biden's tyrannical mandate threatens to cripple American society – from law enforcement to airlines to commercial supply chains to hospitals. It's already happening. But the good news is that huge numbers of "yesterday's heroes" are now fighting back – bravely and boldly. The whole epic showdown is laid out as never before in the sensational October issue of WND's monthly Whistleblower magazine, titled "THE GREAT AMERICAN REBELLION: 'We will not comply!' COVID-19 power grab ignites bold new era of national defiance."



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EXHIBIT 4



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
State Public Health Officer & Director

State of California—Health and Human
Services Agency
**California Department of
Public Health**



GAVIN NEWSOM
Governor

January 8, 2022

AFL 21-08.7

TO: General Acute Care Hospitals (GACHs)
Acute Psychiatric Hospitals (APHs)
Skilled Nursing Facilities (SNFs)

SUBJECT: Guidance on Quarantine and Isolation for Health Care Personnel (HCP) Exposed to SARS-CoV-2 and Return to Work for HCP with COVID-19
(This AFL supersedes AFL 21-08.6)

All Facilities Letter (AFL) Summary

- The purpose of this AFL is to provide hospitals and SNF with updated guidance on:
 - Exposure risk assessment and work restriction for asymptomatic HCP with SARS-CoV-2 exposures (quarantine)
 - Work restrictions for HCP diagnosed with SARS-CoV-2 infection (isolation)
 - This revision incorporates updated Centers for Disease Control and Prevention (CDC) guidance on Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 and Strategies to Mitigate Healthcare Personnel Staffing Shortages.
 - Pursuant to Welfare and Institutions Code section 14126.033 a SNF's receipt of the annual increase in the weighted average Medi-Cal reimbursement rate may be conditioned on the facility's good faith compliance with CDPH AFLs related to the COVID-19 Public Health Emergency, as a result the recommendations included in this AFL are requirements for SNFs.
- From January 8, 2022 until February 1, 2022, HCP who test positive for SARS-CoV-2 and are asymptomatic, may return to work immediately without isolation and without testing, and HCPs who have been exposed and are asymptomatic may return to work immediately without quarantine and without testing. These HCPs must wear an N95 respirator for source control.

With the increasing number of COVID-19 cases from the Omicron variant and in preparation for an anticipated surge in patients, CDC updated their guidance for HCP isolation and quarantine to reflect what is currently known about infection and exposure in the context of vaccination and booster doses. Additionally, CDC updated their guidance for contingency and crisis management to mitigate the effects of staff shortages caused by COVID-19 on patient care. SARS-CoV-2 is an airborne pathogen, infectious persons are commonly asymptomatic, and the Omicron variant is extremely more contagious than the Delta variant.

In AFL 21-08.6, CDPH aligned with CDC's shortened duration of isolation and testing considerations for SARS-CoV-2 infected HCP and consolidated the CDC's conventional, contingency and crisis framework into "routine" and "critical staffing shortage" scenarios to reflect the current status of California healthcare facility staffing levels. At this time, all healthcare facilities should be planning for staffing shortages by adjusting staff schedules, hiring additional HCP, rotating HCP to positions that support patient care activities, identifying roles that can be cross-covered by those not specifically assigned to a role, and developing regional plans to identify designated healthcare facilities or alternate care sites with adequate staffing to care for patients with SARS-CoV-2 infection. The duration of work restrictions and negative test criteria in the table below reflect CDPH recommendations; facilities and LHDs always have the option to implement more protective procedures and follow prior guidance for a longer (10-day) isolation period for infected or a longer (10-day) quarantine for exposed HCP.

Temporary Isolation, Quarantine and Return to Work Criteria for HCP

Due to the critical staffing shortages currently being experienced across the health care continuum because of the rise in the Omicron variant, effective January 8, 2022 through February 1, 2022, CDPH is temporarily adjusting the return-to-work criteria. During this time, this guidance will supersede the tables below.

During this time, HCPs who have tested positive for SARS-CoV-2 and are asymptomatic may return to work immediately without isolation and without testing, and HCPs who have been exposed and are asymptomatic may return to work immediately without quarantine and without testing. These HCPs must wear an N95 respirator for source control. Facilities implementing this change must have made every attempt to bring in additional registry or contract staff and must have considered modifications to non-essential procedures.

These HCPs should preferably be assigned to work with COVID-19 positive patients. However, this may not always be possible in settings such as the emergency department in which you may not know which patients are COVID-19 positive or in areas where you may be experiencing extreme staffing shortages.

Exposure Risk Assessment for HCP

Hospitals should and SNFs must use the CDC's updated risk assessment framework to determine exposure risk for HCP with potential exposure to patients, residents, visitors, and other HCP with confirmed COVID-19 in a health care setting. CDC's updated definition of higher-risk exposure includes use of a facemask by HCP (instead of a respirator) while caring for an infected patient who is not also wearing a facemask or cloth mask. CDC guidance for assessing travel and community-related exposures should continue to be applied to HCP with potential exposures outside of work (e.g., household,) and among HCP exposed to each other while working in non-patient care areas (e.g., administrative offices). For the purpose of contact tracing to identify exposed HCP, the exposure period for the source case begins from two days before the onset of symptoms or, if asymptomatic, two days before test specimen collection for the individual with confirmed COVID-19.

Isolation, Quarantine and Work Restriction for HCP

The highlighted sections below are temporarily waived from January 8, 2022 to February 1, 2022.

Hospitals should and SNFs must use the table, below, to guide work restrictions for HCP with SARS-CoV-2 infection and for asymptomatic HCP with exposures based upon HCP vaccination status and facility staffing level.

Work Restrictions for HCP with SARS-CoV-2 Infection (Isolation)

Vaccination Status	Routine	Critical Staffing Shortage
Boosted, OR Vaccinated but not booster-eligible	5 days* with negative diagnostic test [†] same day or within 24 hours prior to return OR 10 days without a viral test	<5 days with most recent diagnostic test [†] result to prioritize staff placement [‡]
Unvaccinated, OR Those that are vaccinated and booster-eligible but have not yet received their booster dose	7 days* with negative diagnostic test [†] same day or within 24 hours prior to return OR 10 days without a viral test	5 days with most recent diagnostic test [†] result to prioritize staff placement [‡]

Work Restrictions for Asymptomatic HCP with Exposures (Quarantine)

Vaccination Status	Routine	Critical Staffing Shortage
Boosted, OR Vaccinated but not booster-eligible	No work restriction with negative diagnostic test [†] upon identification and at 5-7 days	No work restriction with diagnostic test [†] upon identification and at 5-7 days
Unvaccinated [§] , OR Those that are vaccinated and booster-eligible but have not yet received their booster dose [§]	7 days with diagnostic test [†] upon identification and negative diagnostic test [†] within 48 hours prior to return	No work restriction with diagnostic test [†] upon identification and at 5-7 days

*Asymptomatic or mildly symptomatic with improving symptoms, and meeting negative test criteria; facilities should refer to CDC guidance for HCP with severe to critical illness or moderately to severely immunocompromised.

[†] Either an antigen test or nucleic acid amplification test (NAAT) can be used. Some people may be beyond the period of expected infectiousness but remain NAAT positive for an extended period. Antigen tests typically have a more rapid turnaround time but are often less sensitive than NAAT. Antigen testing is preferred for discontinuation of isolation and return-to-work for SARS-CoV-2 infected HCP and for HCP who have recovered from SARS-CoV-2 infection in the prior 90 days; NAAT is also acceptable if done and negative within 48h of return.

[‡] If most recent test is positive, then HCP may provide direct care only for patients/residents with confirmed SARS-CoV-2 infection, preferably in a cohort setting.

[§] Includes persons with prior infection.

HCP whose most recent test is positive and are working before meeting routine return-to-work criteria must maintain separation from other HCP as much as possible (for example, use a separate breakroom and restroom) and wear a N95 respirator for source control at all times while in the facility. Similarly, exposed unvaccinated and vaccinated HCP who are booster-eligible but have not yet received their booster dose who are working during their quarantine period should also wear a N95 respirator for source control at all times while in the facility until they meet routine return-to-work criteria. In addition, healthcare facilities should make N95 respirators available to any HCP who wishes to wear one when not otherwise required for the care of patients or residents with suspected or confirmed COVID-19.

These recommendations will be updated as additional information becomes available, including regarding the ability of currently authorized vaccines to protect against infection with novel variants and the effectiveness of additional authorized vaccines. This could result in additional circumstances when work restrictions for HCP are recommended.

If you have any questions regarding this AFL, quarantine guidance, or work restrictions, please contact CDPH Healthcare-Associated Infections Program via email at CovHAI@cdph.ca.gov.

If you have any questions about this AFL, please contact your local district office.

Sincerely,

Original signed by Cassie Dunham

Cassie Dunham

Acting Deputy Director

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA
95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)



Page Last Updated : January 8, 2022

EXHIBIT 5



COVID-19

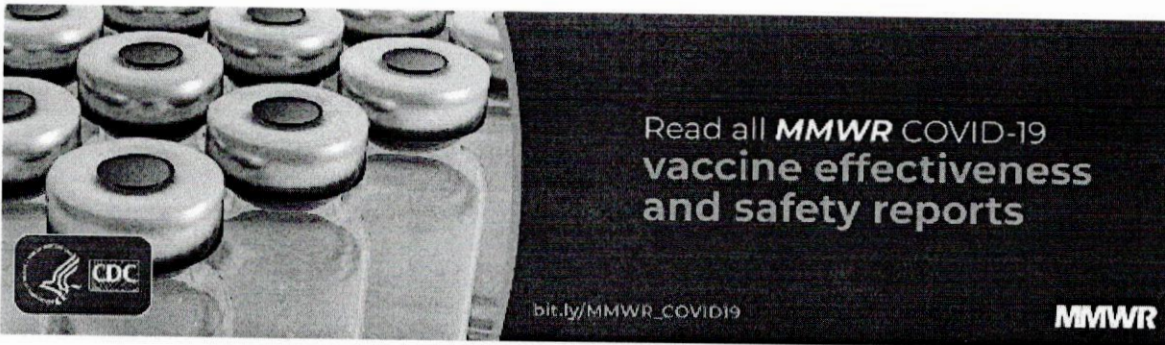
The Possibility of COVID-19 after Vaccination: Breakthrough Infections

Updated Dec. 17, 2021

COVID-19 vaccines are effective at preventing infection, serious illness, and death. **Most people who get COVID-19 are unvaccinated.** However, since vaccines are not 100% effective at preventing infection, some people who are fully vaccinated will still get COVID-19.

An infection of a fully vaccinated person is referred to as a “vaccine breakthrough infection.”

Bottom Line: COVID-19 vaccines protect everyone ages 5 years and older against severe illness, including disease caused by the Delta variant and other variants circulating in the United States.



Key Points

- COVID-19 vaccines protect everyone ages 5 years and older from getting infected and severely ill, and significantly reduce the likelihood of hospitalization and death.
- Getting vaccinated is the best way to slow the spread of COVID-19 and to prevent infection by Delta or other variants.
- A vaccine breakthrough infection happens when a fully vaccinated person gets infected with COVID-19. People with vaccine breakthrough infections may spread COVID-19 to others.
- Even if you are fully vaccinated, if you live in an area with substantial or high transmission of COVID-19, you – as well as your family and community – will be better protected if you wear a mask when you are in indoor public places.
- People who are immunocompromised may not always build adequate levels of protection after an initial 2-dose primary mRNA COVID-19 vaccine series. They should continue to take all precautions recommended for



COVID-19

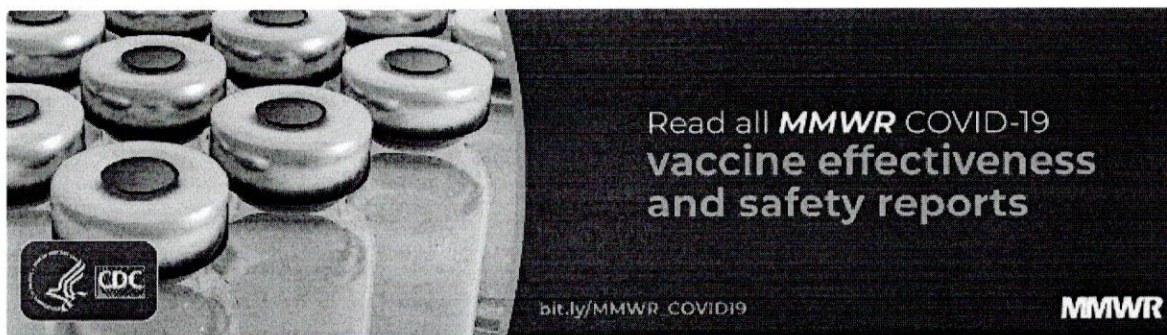
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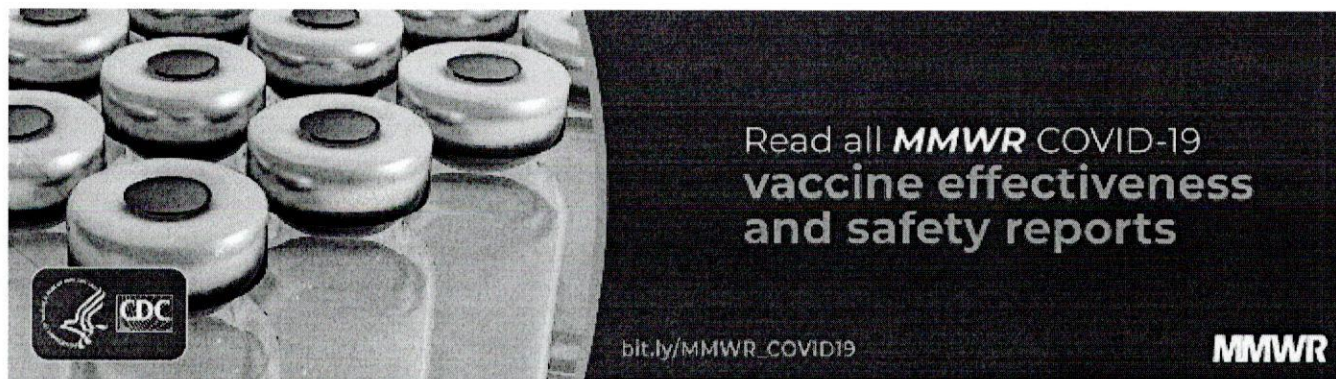
The Possibility of COVID-19 after Vaccination: Breakthrough Infections

Updated Dec. 17, 2021

COVID-19 vaccines are effective at preventing infection, serious illness, and death. **Most people who get vaccinated are not** unvaccinated. However, since vaccines are not 100% effective at preventing infection, some people who are vaccinated will still get COVID-19.

An infection of a fully vaccinated person is referred to as a “vaccine breakthrough infection.”

Bottom Line: COVID-19 vaccines protect everyone ages 5 years and older against severe illness, including those caused by the Delta variant and other variants circulating in the United States.



Key Points

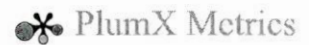
- COVID-19 vaccines protect everyone ages 5 years and older from getting infected and severely ill, and reduce the likelihood of hospitalization and death.

EXHIBIT 6

CORRESPONDENCE | VOLUME 22, ISSUE 1, P16, JANUARY 01, 2022

Transmissibility of SARS-CoV-2 among fully vaccinated individuals

Carlos Franco-Paredes  Published: January, 2022 • DOI: [https://doi.org/10.1016/S1473-3099\(21\)00768-4](https://doi.org/10.1016/S1473-3099(21)00768-4)



Vaccine effectiveness studies have conclusively demonstrated the benefit of COVID-19 vaccines in reducing individual symptomatic and severe disease, resulting in reduced hospitalisations and intensive care unit admissions.¹ However, the impact of vaccination on transmissibility of SARS-CoV-2 needs to be elucidated. A prospective cohort study in the UK by Anika Singanayagam and colleagues² regarding community transmission of SARS-CoV-2 among unvaccinated and vaccinated individuals provides important information that needs to be considered in reassessing vaccination policies. This study showed that the impact of vaccination on community transmission of circulating variants of SARS-CoV-2 appeared to be not significantly different from the impact among unvaccinated people.^{2, 3} The scientific rationale for mandatory vaccination in the USA relies on the premise that vaccination prevents transmission to others, resulting in a “pandemic of the unvaccinated”.⁴ Yet, the demonstration of COVID-19 breakthrough infections among fully vaccinated health-care workers (HCW) in Israel, who in turn may transmit this infection to their patients,⁵ requires a reassessment of compulsory vaccination policies leading to the job dismissal of unvaccinated HCW in the USA. Indeed, there is growing evidence that peak viral titres in the upper airways of the lungs and culturable virus are similar in vaccinated and unvaccinated individuals.^{2,3,5-7} A recent investigation by the US Centers for Disease Control and Prevention of an outbreak of COVID-19 in a prison in Texas showed the equal presence of infectious virus in the nasopharynx of vaccinated and unvaccinated individuals.⁶ Similarly, researchers in California observed no major differences between vaccinated and unvaccinated individuals in terms of SARS-CoV-2 viral loads in the nasopharynx, even in those with proven asymptomatic infection.⁷ Thus, the current evidence suggests that current mandatory vaccination policies might need to be reconsidered, and that vaccination status should not replace mitigation practices such as mask wearing, physical distancing, and contact-tracing investigations, even within highly vaccinated populations.

I declare no competing interests.

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